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10/009,389	07/20/2002	John Reynolds	P1646USA	7079

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 11/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/009,389

Applicant(s)

REYNOLDS, JOHN

Examiner

Georgia L. Helmer

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,3-9 and 11-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-9 and 11-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>13 Aug 2004</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1638

## **DETAILED ACTION**

### ***Status of the Claims***

1. The Office acknowledges receipt of Applicants Response; dated 13 August 2004.

2. Applicant has cancelled claims 2 and 10, and amended claims 1, 3-9 and 11-15.

Claims 1, 3-9 and 11-15 are pending, and are examined in the instant action.

3. All rejections not addressed below have been withdrawn.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Information Disclosure Statement***

5. Applicant's IDS, form 1449, filed 13 August 2004 is acknowledged and a signed copy included with the Office Action.

### ***Claim Rejections - 35 USC § 101***

6. Claims 8 and 15 remain rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, for reasons of record.

Applicant has amended claim 8 to recite " Allium plant or plant tissue transformed by the method of claim 1 and progeny thereof *under said selective conditions*".

Applicant has amended claims 15 to recite " Allium plant or plant tissue transformed by the method of claim 9 and progeny thereof *under said selective conditions*". The amendment "under selective conditions" does not modify "progeny", it modifies "plant of plant tissue transformed by the method of claim 1". Also, "selective conditions" is fairly meaningless in the absence of a recitation that the selective conditions are selective for

Art Unit: 1638

a marker gene present in the transformed plant. Suggested is the insertion of --transformed— before “progeny” and the deletion of “under said selective conditions”.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 15 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Claims 8 and 15 are indefinite in their recitation of “plant or plant tissue...and progeny” which employs improper Markush terminology. Replacement of the “and “ before “progeny” with --or-- would obviate this rejection. See MPEP 2173.05(h).

Furthermore, claims 8 and 15 are indefinite in their recitation of “progeny thereof under selective conditions”, which is grammatically awkward. It is unclear whether “said selective conditions” modifies “the method of claim 1” or the “progeny”. Modification of “progeny” by this phrase makes no sense. The phrase “under said selective conditions” should be deleted.

***Claim Rejections - 35 USC § 112-1 written description***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

Art Unit: 1638

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6 and 13 are drawn to the "method ... wherein the heterologous gene is a modified EPSPS"... There is no structural description of "modified". "Modified" can have many definitions, including mutations, inversions, deletions, duplications, substitutions, as well as including introns, exons, non-coding regions of any size and compositions and rearrangements of the above. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

"A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus."

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . . Accordingly, the specification does not provide a written description of the invention . . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed. (see Written Description Requirement published in Federal Register/Vol.66, No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111.)

***Claim Rejections - 35 USC § 112 Enablement***

9. Claims 1, 3-9 and 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record (Office Action of 25 February 2004).

Applicant's arguments filed 13 August 2002 have been fully considered but they are not persuasive.

Applicant (Response, p. 9-10) " is confused as to Examiner's statement Applicant has not provided a single working example of Agrobacterium transformation of *Allium cepa* using embryogenic callus derived from immature embryos or flower buds", further citing "Applicant's examples are detailed". Applicant's traversal is unpersuasive. Examiner's statement is "Applicant's prophetic examples are detailed *but lack any showing of exemplified transgenic Allium cepa plant material, plants, or progeny.*" Applicant acknowledges that although no regenerated transformed plants are described, adequate guidance has been given (Response, p. 12).

Applicant is invited to supply clarification and other information, preferably as a Rule 1.132 Declaration, about Applicant's results with the claimed invention. This declaration should demonstrate that only those techniques and starting materials set forth in the specification were relied upon.

Applicant traverses saying primarily (Response, p. 14) that "the specification clearly discloses the plant tissue is derived from immature embryos". Applicant's traversal is unpersuasive . Although the claims are interpreted in light of the

Art Unit: 1638

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant traverses (Response, p. 16-17) with respect to the rejection of “modified EPSPs gene”, the specification describes the gene and the function of the gene. Applicant's traversal is unpersuasive. In view of the lack in the specification , of any specialized definition that would restrict the claimed invention to a specific “modified” EPSP gene, the limitation of the specification are not read into the claims. See *In re Paulsen (CAFC)* 31 USPQ2d 1671 (8/3/94).

Applicant asserts (Response, p. 18) that “Examiner cites a source stating that plant transformation procedures employing tissue culture are unpredictable and early attempts have failed for her basis in rejecting the claims” as being an improper basis for rejection. Applicant's traversal is unpersuasive. Applicant is making a conclusionary statement without evidentiary support. Applicant is encouraged to consult MPEP 2164.01(a)) item (E), recited below.

Art Unit: 1638

**2164.01(a) Undue Experimentation Factors**

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue.” These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and

- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

*In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO’s determination that claims directed to methods for detection of hepatitis E surface antigens did not satisfy the enablement requirement). In *Wands*, the court noted that there was no disagreement as to the facts, but merely a disagreement as to the interpretation of the data and the conclusion to be made from the facts. *In re Wands*, 858 F.2d at 736-40, 8 USPQ2d at 1403-07. The Court held that the specification was enabling with respect to the claims at issue and found that “there was considerable direction and guidance” in the specification; there was “a high level of skill in the art at the time the application was filed;” and “all of the methods needed to practice the invention were well known.” 858 F.2d at 740, 8 USPQ2d at 1406. After considering all the factors related to the enablement issue, the court concluded that “it would not require undue experimentation to obtain antibodies needed to practice the claimed invention.” *Id.*, 8 USPQ2d at 1407.



***Claim Rejections - 35 USC § 102***

10. Claims 8 and 15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Dommissee, et. al., Onion is a Monocotyledonous Host for Agrobacterium. Plant Science, vol. 69 (1990) pages 249-257; Applicant's IDS.

Applicant's arguments that Dommissee et. al. do not teach the use of embryogenic callus of Allium (Response, p. 19-20) have been fully considered but they are not persuasive. Claims 8 and 15 are product by process claims, wherein the product is a Allium plant transformed by the method of claim 1, and progeny thereof. These products are not distinguishable from an Allium plant transformed by the prior art method of Dommissee. See In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Accordingly, Dommissee et. al. anticipates the claimed invention.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1638

12. Claims 1, 3-9 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eady, et. al., Transformation of Onion (*Allium cepa* L.)1998, Proceedings National Onion Research Conference, Sacramento, CA USA, December 10-12, 1998 (IDS), hereafter referred to as "Eady-1"), in view of Eady et. al., A comparison of four selective agents to use with *Allium cepa* immature embryos and immature embryo-derived cultures, Plant Cell Reports, 1998, vol. 18, pages 117-121, (hereafter referred to as "Eady-2"), and applicant's admitted prior art.

Eady-1 teaches a method of transforming immature embryos (line 3) of *Allium cepa* (line 2) with *Agrobacterium tumefaciens* (line 1) (claim 3) containing a *m-gfp-ER* gene and a *nptII* gene to obtain transformed *Allium cepa* plants (lines 10-12) under selective conditions (lines 8-10) (claims 8 and 15).

The *m-gfp-ER* gene, a modified green fluorescent protein reporter gene, and the *nptII* antibiotic resistance gene, are heterologous to *Allium cepa*. The *Agrobacterium* used contained a T-DNA, (line 6) implying the presence of a Ti plasmid (claim 4).

Eady-1 does not teach the use of embryogenic callus of *Allium cepa*, an ESPS gene, or a temperature of 25-30 degrees C.

Eady-2 teaches the use of embryogenic callus derived from immature embryo of *Allium cepa* (Materials & methods, 1<sup>st</sup> ¶, p. 118)(claim 1, 7, 9), the culture temperature of 26 degrees C ((Materials & methods, 3<sup>rd</sup> ¶, p. 118)(claim 11), and a culture time of

Art Unit: 1638

2-6 months (Materials & methods, 4th ¶, p. 118) (claim 9). Eady-2 also suggest the use of Allium embryogenic callus in a transformation protocol (p. 117, column 2, top ¶).

Applicant's admitted prior art (specification p. 5, lines 4-12) teaches the successful use of EPSP genes and modified EPSP genes in plant transformation.

It would have been obvious to one of skill in the art, at the time of the invention was made, to use the embryogenic callus of Eady-2 in the transformation method of Eady-1 and to substitute the *m-gfp-ER* gene and a *nptII* gene of Eady-1 with the EPSP genes and modified EPSP genes of Applicants admitted prior art, as the EPSP genes and modified EPSP genes has been show to function well for plant transformation. One skilled in the art would have been motivated to so, with a reasonable expectation of success, given the suggestion by Eady-2 and the success of Eady-1.

Accordingly, the claimed invention is prima facie obvious in view of the prior art.

### **Remarks**

13. No claims are allowed.

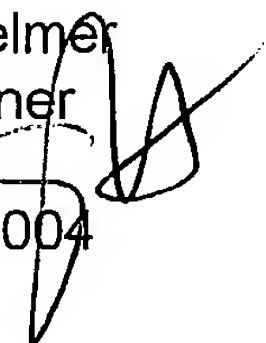
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0976. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1638

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer  
Patent Examiner  
Art Unit 1638  
October 29, 2004



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